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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,095	09/18/2003	Robert P. Hammer	Hammer 0212.1	6953

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PATENT DEPARTMENT
TAYLOR, PORTER, BROOKS & PHILLIPS, L.L.P
P.O. BOX 2471
BATON ROUGE, LA 70821-2471

EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,095	HAMMER ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-18,20,21 and 51-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,8,20,21,51-53 and 55* is/are rejected.

7)☒ Claim(s) *4,9-18 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 53 and 54 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/412,081 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

Instant claims 1, 4, 7-18, 20, 21, 51, 52, and 55 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/412,081 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose all of the generic formulas recited in instant claims 1 and 51; does not disclose the additional functionalities of instant claim 1, part (d); does not disclose the size limitations of instant claim 1, part (e); does not disclose compounds corresponding to SEQ ID NOS:5, 6, and 7; does not disclose aggregation-inducing sequences corresponding to SEQ ID NOS:9-16 or Q_m where m is an integer from 25 to 45; and does not disclose combining the compounds with a pharmaceutically acceptable carrier in general. Note that unless a claim is limited exclusively to subject matter disclosed in a priority application, the claim is not entitled to the benefit of the filing date of the priority application. See MPEP 201.11(I) and (VI).

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 7, 8, 20, 51, 52, and 55 are rejected under 35 U.S.C. 102(b) and claim 53 is rejected under 35 U.S.C. 102(a) as being anticipated by the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001). The Fu et al article teaches Applicants' elected peptide, Lys-Digb-Val-Dbzg-Phe-Dpg-$(Lys)_6$-NH_2. See page 239, column 1. This peptide corresponds to, e.g., the sixth peptidyl sequence of amended claim 1 wherein the N-terminal end comprises Lys that does not adversely affect the compound's ability to inhibit the

toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, Y_{AA1} is Digb, X_{aa1} is Val, Y_{AA2} is Dbzg, X_{aa2} is Phe, Y_{AA3} is Dpg, and $(S)_n$ is Lys_6-NH_2 where n=6. This peptide corresponds to, e.g., the ninth peptidyl sequence of amended claim 1 wherein the N-terminal end comprises Lys that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, Y_{AA1} is Digb, X_{aa1} is Val, Y_{AA2} is Dbzg, X_{aa2} is Phe, Y_{AA3} is Dpg, X_{aa3} is Lys, and $(S)_n$ is Lys_5-NH_2 where n=5. This peptide also corresponds to, e.g., the first peptidyl sequence of claim 53 wherein X_{aa1} is Lys, Y_{AA1} is Digb, X_{aa2} is Val, Y_{AA2} is Dbzg, X_{aa3} is Phe, and $(S)_n$ is Dpg-Lys_6-NH_2 where n=7. Note that Applicants' definition of $(S)_n$ states that the hydrophilic region comprises hydrophilic amino acids or other hydrophilic groups, i.e. can comprise non-hydrophilic amino acids and groups as long as the region as a whole is hydrophilic. This peptide also corresponds to, e.g., the second peptidyl sequence of claim 53 wherein X_{aa1} is Lys, Y_{AA1} is Digb, X_{aa2} is Val, Y_{AA2} is Dbzg, X_{aa3} is Phe, n=0, and the C-terminal end comprises an additional functionality (i.e. Dpg-Lys_6-NH_2) that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality.

4. Claims 1, 7, 8, 20, 21, 51, 52, and 55 are rejected under 35 U.S.C. 102(a) as being anticipated by the Fu dissertation (Louisiana State University, December 2002). The Fu dissertation teaches the peptide AMY-3 at page 126 which comprises the same peptidyl sequences recited in instant claim 1. For example, AMY-3 of the Fu dissertation corresponds to the sixth peptidyl sequence of claim 1 wherein Y_{AA1} is Dpg, X_{aa1} is Phe, Y_{AA2} is Dbzg, X_{aa2} is

Val, Y_{AA3} is Dibg, and (S) is Lys and n=7. Alternatively, AMY-3 corresponds to the ninth peptidyl sequence of claim 1 wherein Y_{AA1} is Dpg, X_{aa1} is Phe, Y_{AA2} is Dbzg, X_{aa2} is Val, Y_{AA3} is Dibg, X_{aa3} is Lys, (S) is Lys, and n=6. In view of the similarity in structure between the peptide of the Fu dissertation and Applicants' claimed peptidyl sequences, the peptide of the dissertation inherently will be capable of inhibiting the toxicity of an amyloid protein or amyloid peptide to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present the peptide of the Fu dissertation and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that the claimed compounds are unobviously different than the peptides of the Fu dissertation. Note that patentability is not imparted to product claims merely upon the employment of descriptive language not chosen by the prior art. In re Skoner, 186 USPQ 80, 82 (CCPA 1975). The discovery of a new property or use for a previously known compound can not impart patentability to claims drawn to the compound. In re Schoenwald, 22 USPQ2d 1671 (CAFC 1992). The Fu dissertation also teaches the peptide AMY-1, which corresponds to Applicants' elected SEQ ID NO:4 and which is combined with a phosphate-buffered aqueous solution. See pages 103 and 108. The AMY-1 peptide corresponds to corresponds to, e.g., the sixth peptidyl sequence of amended claim 1 wherein the N-terminal end comprises Lys that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, Y_{AA1} is Digb, X_{aa1} is Val, Y_{AA2} is Dbzg, X_{aa2} is Phe, Y_{AA3} is Dpg, and $(S)_n$ is Lys_6-NH_2 where n=6. This peptide corresponds to, e.g., the ninth peptidyl sequence of amended claim 1 wherein the N-terminal end comprises Lys that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared

to an otherwise identical compound lacking such additional functionality, Y_{AA1} is Digb, X_{aa1} is Val, Y_{AA2} is Dbzg, X_{aa2} is Phe, Y_{AA3} is Dpg, X_{aa3} is Lys, and $(S)_n$ is Lys_5-NH_2 where n=5.

5. Claims 1, 7, 8, 20, 21, 51, 52, and 55 are rejected under 35 U.S.C. 102(a) as being anticipated by the Aucoin oral presentation, "Dissection of an Amyloid Aggregation Inhibitor", 225th American Chemical Society conference, New Orleans, LA, March 23-27, 2003. The Aucoin oral presentation, as evidenced by the presentation notes supplied in the Information Disclosure Statement filed September 18, 2003, disclosed peptides AMY-1 and AMY-3 which correspond to Applicants' claimed compounds of SEQ ID NOS:4 and 6, respectively. The peptides are combined with a phosphate-buffered aqueous solution, which corresponds to Applicants' pharmaceutically acceptable carrier.

AMY-3 corresponds to the sixth peptidyl sequence of amended claim 1 wherein Y_{AA1} is Dpg, X_{aa1} is Phe, Y_{AA2} is Dbzg, X_{aa2} is Val, Y_{AA3} is Dibg, and (S) is Lys and n=7. Alternatively, AMY-3 corresponds to the ninth peptidyl sequence of claim 1 wherein Y_{AA1} is Dpg, X_{aa1} is Phe, Y_{AA2} is Dbzg, X_{aa2} is Val, Y_{AA3} is Dibg, X_{aa3} is Lys, (S) is Lys, and n=6. AMY-1 corresponds to corresponds to, e.g., the sixth peptidyl sequence of amended claim 1 wherein the N-terminal end comprises Lys that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, Y_{AA1} is Digb, X_{aa1} is Val, Y_{AA2} is Dbzg, X_{aa2} is Phe, Y_{AA3} is Dpg, and $(S)_n$ is Lys_6-NH_2 where n=6. This peptide corresponds to, e.g., the ninth peptidyl sequence of amended claim 1 wherein the N-terminal end comprises Lys that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared

to an otherwise identical compound lacking such additional functionality, Y_{AA1} is Digb, X_{aa1} is Val, Y_{AA2} is Dbzg, X_{aa2} is Phe, Y_{AA3} is Dpg, X_{aa3} is Lys, and $(S)_n$ is Lys_5-NH_2 where n=5.

The Aucoin oral presentation satisfies the requirement of 35 U.S.C. 102(a) that an invention be "known... by others in this country" because the identity of the presenter is different than the inventorship of the instant application, and any difference in authorship/inventorship satisfies the statutory requirement of "by another". See MPEP 2132(III). See also Ecolochem Inc. v. Southern California Edison, 56 USPQ2d 1065, 1071 (CAFC 2002), where the court acknowledges that oral presentations can satisfy the requirements of 35 U.S.C. 102(a). This rejection could be overcome, e.g., by the submission of a declaration under 37 CFR 1.132 showing that the subject matter of the presentation was derived from the instant inventors and was therefore not "by another". See MPEP 715.01(c), 716.10, and 2136.05.

Note that the Aucoin oral presentation is not considered to be a printed publication because insufficient evidence is of record as to whether printed copies, slides, etc. of oral presentation were made available and/or whether members of the public had time to make copies of the disclosed subject matter. Compare In re Klopfenstein, 72 USPQ2d 1117 (CAFC 2004).

6. Applicant's arguments filed January 16, 2007 have been fully considered but they are not persuasive.

The rejection of claim 1 and certain of its dependent claims over the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001) is maintained. As noted in the previous Office action, there are many possible correlations between the peptide of the Fu et al article and Applicants' different peptidyl sequences. While amended claim 1 removes several of those correspondences, it does not remove all of them.

The rejection over the Aucoin oral presentation, "Dissection of an Amyloid Aggregation Inhibitor", 225th American Chemical Society conference, New Orleans, LA, March 23-27, 2003, is maintained for the reasons of record. In determining whether the "by others" clause of 35 U.S.C. 102(a) is satisfied, two inquiries must be made: (1) who is the inventor/author of the subject matter being applied as a reference; and (2) who is the inventor of the claims which are being rejected. The Hammer affidavit filed December 23, 2005 answers the first inquiry, i.e. shows that the sequence and synthesis of peptides AMY-1 and AMY-3 was conceived by Drs. Hammer, McLaughlin, Fu, and Miller. The examiner has never questioned the substance of this showing in the Hammer affidavit. As to the second inquiry, no evidence has been submitted as to who among the six inventors named in the oaths under 37 CFR 1.63 are the inventors of the subject matter of rejected claims 1, 7, 8, 20, 21, 51, 52, and 55. Accordingly, the examiner assumes that all six inventors named in the oaths under 37 CFR 1.63 are the inventors of the subject matter of rejected claims 1, 7, 8, 20, 21, 51, 52, and 55. While this might not be a particularly strong presumption in light of 35 U.S.C. 116, even a weak presumption preponderates when no evidence to the contrary is of record. Note that, in contrast to claim 54, the rejected claims embrace subject matter in addition to peptides AMY-1 and AMY-3. Accordingly, it can not be presumed that Drs. Hammer, McLaughlin, Fu, and Miller are the only inventors of the subject matter claimed in claims 1, 7, 8, 20, 21, 51, 52, and 55. As suggested in the last paragraph of page 5 of Applicants' Remarks, this is one of those situations in which a question has arisen in prosecution in which it has "become genuinely important to distinguish who is actually an inventor on which claims." In order to exclude the Aucoin oral presentation as prior art under 35 U.S.C. 102(a), Applicants must next establish that Drs. Hammer,

McLaughlin, Fu, and Miller are the only inventors of the subject matter claimed in claims 1, 7, 8, 20, 21, 51, 52, and 55. Once this is established, the reference will no longer satisfy the "by others" requirement of 35 U.S.C. 102(a). If it is not possible to establish that Drs. Hammer, McLaughlin, Fu, and Miller are the only inventors of the subject matter claimed in claims 1, 7, 8, 20, 21, 51, 52, and 55, then Applicants will have to overcome the rejection by other means, e.g., amendment of the claims, declaration under 37 CFR 1.131, etc.

For analogous reasons, the rejection of claim 53 over the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001) and the rejection of claims 1, 7, 8, 20, 21, 51, 52, and 55 over the Fu dissertation (Louisiana State University, December 2002) are maintained. Based upon the evidence of record, the subject matter disclosed in these references and relied upon in the rejections is "by another" and available as prior art against the instant claims under 35 U.S.C. 102(a). Contrary to the first full paragraph at page 11 of Applicants' Remarks, there is a logical reason to continue to cite the Fu et al article against independent claim 53: aside from the oaths under 37 CFR 1.63, there is no evidence of record as to who are the actual inventors of the subject matter of claim 53. Because independent claim 53 embraces many more compounds than the single compound embraced by dependent claim 54, it can not be presumed that the inventors of the single compound of claim 54 are the only inventors of the many compounds of claim 53.

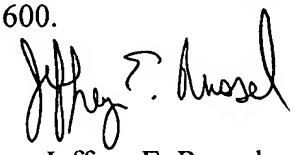
7. Claims 4, 9-18, and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
February 15, 2007